

10/813721

COJE

Attorney Docket No. 00027.05CON

	IN THE UNITED STATES PATENT	(AN	D TRADEMARK OFFICE
In re a	pplication of: Joshua D. Rabinowitz, et al.)	
)	
Patent No.: 7,022,312)	Examiner: M. Haghighatian
)	
Issue Date: April 4, 2006)	Group Art Unit: 1616
)	•
For:	DELIVERY OF ANTIEMETICS)	Certificate
	THROUGH AN INHALATION ROUTE)	Certificate
			APR 2 4 2006
Attn:	Certificate of Correction Branch		
Commissioner for Patents			of Correction
P.O. B	ox 1450		0. 0 (
Alexa	ndria VA 22313-1450		

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR PTO MISTAKE (37 CFR 1.322(a))

- 1. Attached is Form PTO/SB/44, which is suitable for printing.
- 2. The exact location where the error occurred is in the Claims, column 14, line 55, as follows:

Claim 9 reads:

9. The condensation aerosol according to Claim 8, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

Claim 9 should read:

- 9. The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of about 0.2 to about 3 microns.
- 3. These changes were submitted in an Amendment Under 37 C.F.R. § 1.312(a) filed on January 18, 2006. A copy of this Amendment together with a copy of the date-stamped postcard receipt is enclosed. The minor errors, described above, were incurred through the fault of the Office and therefore no fee is believed due.

37 CFR 1.8 CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington, D.C. 2023 on April 17, 2006.

Name:

eronica Doucet

APR 24 2006

Entry of this Certificate of Correction is respectfully requested.

Please send the Certificate to:

7

Swanson & Bratschun, L.L.C. 1745 Shea Center Drive, Suite 330 Highlands Ranch, Colorado 80129

This constitutes authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

Respectfully submitted,

Katherine Lobel-Rice, # 58,079

Swanson & Bratschun, L.L.C.

1745 Shea Center Drive, Suite 330 Highlands Ranch, Colorado 80129

(303) 268-0066

S:\ClientFolders\Alexza\27.05CON\Request to Correct.doc

<u>4/17/</u>66

PTO/SB/44 (07-03)

Approved for use through 01/31/2004. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. (Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 7,022,312

DATED

: 4/4/2006

Docket No: 00027.05CON

INVENTOR(S) :

Joshua Rabinowitz, Alejandro Zaffaroni

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 21 (renumbered as Claim 9). The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of about 0.2 to about 3 microns.

MAILING ADDRESS OF SENDER: Customer No. 28,571

Swanson & Bratschun, LLC 1745 Shea Center Drive, Suite 330

PATENT NO.

7,022,312

No. of additional copies

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

DATE: January 18, 2006 APPLICANT: Rabinowitz et al.

APP NO: 10813721

RECEIPT IS HEREBY ACKNOWLEDGED OF:

Part B Fees Transmittal: 1 pg

Amendment Under 37 CFR 1.312(a): 7 pgs

Check in the amount of \$1,000.00



Docket No.

00027.05CON

S:\ClientFolders\Alexza\27.05CON\Card Receipt.doc

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as m

or Fax

37485 75 SWANSON & BJ	RATSCHUN, L.L.C ER DRIVE, SUITE 33	O AP	R 2 0 2006	I hereby certify that the States Postal Service addressed to the Maj trapemitted to the USP	rtificate of M his Fee(s) Tra with sufficien y Stop ISSU TO (571) y	leiling or Trens	or domestic mailings of the for any other accompanying ant or formal drawing, must smission g deposited with the United st class mail in an envelope above, or being facsimile late indicated below. (Depositor's name) (Signature)
		<u></u>		January 18.	2006		
APPLICATION NO.	FILING DATE	F	IRST NAMED IN		L	DOCKET NO.	CONFIRMATION NO.
10/813,721 TITLE OF INVENTION: DI	03/31/2004 ELIVERY OF ANTIEMETI	CS THROUGH AN	Joshua D. Rabi INHALATION		. 00027	7.05CON	7409
						•	
APPLN. TYPE	SMALL ENTITY	· ISSUE FE	Ε	PUBLICATION FEE	TOTAL	EE(S) DUE	DATE DUE
nonprovisional	YES	\$700		\$300	\$	1000	01/18/2006
EXAM	INER .	ART UNI	r _	CLASS-SUB CLASS	Ì		
HAGHIGHA	ΠΑΝ, MINA	1616		424-045000	•		
CFR 1.363). Change of correspondent Address form PTO/SB/12	address or indication of "Fe ence address (or Change of (2) 2) attached. on (or "Fee Address" Indica r more recent) attached. Use	Correspondence	(1) the names or agents OR,	on the patent front page, li of up to 3 registered pater alternatively, f a single firm (having as a mey or agent) and the nam tent attorneys or agents. If e will be printed.	nt attorneys		n & Bratschun, l
	RESIDENCE DATA TO BI		**	• • •			
PLEASE NOTE: Unless recordation as set forth in	an assignee is identified be 37 CFR 3.11. Completion of	low, no assignee d f this form is NOT	ata will appear of a substitute for t	on the patent. If an assign iling an assignment.	ee is identifi	ed below, the d	ocument has been filed for
(A) NAME OF ASSIGNE	E	(B)	RESIDENCE: (CITY and STATE OR COL	JNTRY)		
Alexza Pha	rmaceuticals,	Inc.	Palo Al	to, California	ı		
Please check the appropriate	assignee category or categor	ies (will not be prin	ted on the paten	t): 🗖 Individual 🌠 Co	orporation or	other private gro	oup entity Government
Ia. The following fee(s) are expressions. Issue Fee Publication Fee (No sn	nclosed: nall entity discount permitted Copies	i) (Payment by c	e amount of the fee(s) is en redit card. Form PTO-2038	is attached.	uired foo(s) or	credit any overpayment, to

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Typed or printed name Katherine Lobel-Rice Date January 18, 2006

Registration No. 58,079

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

5.



DATE OF NOTICE OF ALLOWANCE: October 18, 2005

Attorney Docket: 00027.05CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Joshua D. Rabinowitz, et al.		Examiner: M. Haghighatian
Serial No.: 10/813,721)	Group Art Unit: 1616
Filing Date: March 31, 2004)	Confirmation No.: 7409
For: DELIVERY OF ANTIEMETICS THROUGH AN INHALATION ROUTE)	
Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		

SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. § 1.312(a)

Sir:

AMENDMENT

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

APR 24 2006

37 CFR 1.8	
CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:	
\sim 11 /1 k3/1	5
Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 223/13/1450/or	24 200
	1 10 75
Signature: Name: Gasha L. Pierce	

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A condensation aerosol for delivery of a drug selected from the group consisting of dolasetron, granisetron and metoclopramide,

wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol, characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

- 2. (previously amended) The condensation aerosol according to Claim 1, wherein the condensation aerosol is formed at a rate greater than 10⁹ particles per second.
- 3. (previously amended) The condensation aerosol according to Claim 2, wherein the condensation aerosol is formed at a rate greater than 10^{10} particles per second.

4.-9. (cancelled)

- 10. (previously amended) A method of producing a drug selected from the group consisting of dolasetron, granisetron and metoclopramide in an aerosol form comprising:
- a. heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and
- b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.
- 11. (previously amended) The method according to Claim 10, wherein the condensation aerosol is formed at a rate greater than 10⁹ particles per second.

12. (previously amended) The method according to Claim 11, wherein the condensation aerosol is formed at a rate greater than 10¹⁰ particles per second.

13.-18. (cancelled)

- 19. (previously presented) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.1 to 5 microns.
- 20. (previously presented) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- 21. (currently amended) The condensation aerosol according to Claim 20 1, wherein the condensation aerosol is characterized by an MMAD of about 0.2 and to about 3 microns.
- 22. (previously presented) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.
- 23. (previously presented) The condensation aerosol according to claim 22, wherein the condensation aerosol is characterized by less than 2.5% drug degradation products by weight.
- 24. (previously presented) The condensation aerosol according to Claim 1, wherein the solid support is a metal foil.
- 25. (previously presented) The condensation aerosol according to Claim 1, wherein the drug is dolasetron.
- 26. (previously presented) The condensation aerosol according to Claim 1, wherein the drug is granisetron.
- 27. (previously presented) The condensation aerosol according to Claim 1, wherein the drug is metoclopramide.

- 28. (previously presented) The method according to Claim 10, wherein the condensation aerosol is characterized by an MMAD of 0.1 to 5 microns.
- 29. (previously presented) The method according to Claim 10, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- 30. (currently amended) The method according to Claim 29 10, wherein the condensation aerosol is characterized by an MMAD of about 0.2 to about 3 microns.
- 31. (previously presented) The method according to Claim 10, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.
- 32. (previously presented) The method according to Claim 31, wherein the condensation aerosol is characterized by less than 2.5% drug degradation products by weight.
- 33. (previously presented) The method according to Claim 10, wherein the solid support is a metal foil.
- 34. (previously presented) The method according to Claim 10, wherein the drug is dolasetron.
- 35. (previously presented) The method according to Claim 10, wherein the drug is granisetron.
- 36. (previously presented) The method according to Claim 10, wherein the drug is metoclopramide.
- 37. (previously presented) A condensation aerosol for delivery of dolasetron, wherein the condensation aerosol is formed by heating a thin layer containing dolasetron, on a solid support, to produce a vapor of dolasetron, and condensing the vapor to form a condensation

aerosol characterized by less than 5% dolasetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

- 38. (previously presented) A condensation aerosol for delivery of granisetron, wherein the condensation aerosol is formed by heating a thin layer containing granisetron, on a solid support, to produce a vapor of granisetron, and condensing the vapor to form a condensation aerosol characterized by less than 5% granisetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.
- 39. (previously presented) A condensation aerosol for delivery of metoclopramide, wherein the condensation aerosol is formed by heating a thin layer containing metoclopramide, on a solid support, to produce a vapor of metoclopramide, and condensing the vapor to form a condensation aerosol characterized by less than 5% metoclopramide degradation products by weight, and an MMAD of about 0.2 to about 3 microns.
- 40. (previously presented) A method of producing dolasetron in an aerosol form comprising:
- a. heating a thin layer containing dolasetron, on a solid support, to produce a vapor of dolasetron, and
- b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 5% dolasetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.
- 41. (previously presented) A method of producing granisetron in an aerosol form comprising:
- a. heating a thin layer containing granisetron, on a solid support, to produce a vapor of granisetron, and
- b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 5% granisetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

- 42. (previously presented) A method of producing metoclopramide in an aerosol form comprising:
- a. heating a thin layer containing metoclopramide, on a solid support, to produce a vapor of metoclopramide, and
- b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 5% metoclopramide degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

<u>REMARKS</u>

A Notice of Allowance was mailed in the above-captioned application on October 18, 2005. The Notice of Allowance included an Examiner's amendment. On October 20, 2005 Applicant filed an Amendment under 37 C.F.R. § 1.312(a) requesting entry of the present amendments that have been made to claims 1 and 21 to correct minor typographical errors. However, the claims presented in that Amendment did not reflect the amendments made in the Examiner's amendment.

This Supplemental Amendment under 37 C.F.R. § 1.312(a) includes the amendments made in the Examiner's amendment, amendments made in the October 20, 2005 filing and additional amendments to claims 21 and 30 to correct dependency. The claims as presented herein reflect the claims as allowed by the Examiner and the amendments sought pursuant to 37 C.F.R. § 1.312(a).

The Examiner is encouraged to call and discuss this case with the undersigned should there be any questions regarding this amendment.

No fees are believed due with this amendment; however, the undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: January 18, 2006

Katherine Lobel-Rice, #58,079 Swanson & Bratschun, L.L.C.

1745 Shea Center Drive, Suite 330 Highlands Ranch, Colorado 80129

Telephone:

(303) 268-0066

Facsimile: (303) 268-0065

S:\CLIENTFOLDERS\ALEXZA\27.05CON\SUPPLEMENTAL AMENDMENT UNDER 312(A)1.DOC